

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

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| IN RE: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION | MDL No. 15-2666 (JNE/FLN) |
| THIS DOCUMENT RELATES TO ALL CASES | |

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF
DR. RICHARD P. WENZEL**

I. PRELIMINARY STATEMENT

This Multidistrict Litigation involves a group of Plaintiffs who underwent total hip replacement or total knee replacement surgery. Following the surgery, the Plaintiffs discovered that they had developed a deep periprosthetic joint infection (“PJI” aka “DJI”).

Plaintiffs maintain that the Bair Hugger forced air warming medical device is capable of causing DJIs. Specifically, Plaintiffs contend that the Bair Hugger device disrupts unidirectional airflow used in most modern operating rooms to help minimize airborne contamination of the surgical site. In addition, Plaintiffs have proffered evidence showing that the Bair Hugger device causes airborne bacteria to contaminate the sterile field during surgery, leading to DJI.

This memorandum of law will address the opinions and report of Defendant 3M’s expert witness Dr. Richard P. Wenzel. Dr. Wenzel has written a report and expressed opinions related to general causation in this case *i.e.*, whether the Bair Hugger forced air warming device is capable of causing periprosthetic joint infections in patients undergoing total knee replacement or total hip replacement surgery. Dr. Wenzel’s opinions are unreliable and irrelevant. Accordingly, and for the reasons that follow, the Court should exclude Dr. Wenzel’s opinions and testimony pursuant to Rule 702 of the Federal Rules of Evidence.

II. LEGAL STANDARD

Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, (1993), govern the admissibility of expert testimony. The *Daubert* standard

applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *See Polski v. Quigley Corp.*, 538 F.3d 836, 838 (8th Cir. 2008). Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Id. “[I]t is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case.” *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001). “Once initial expert qualifications and usefulness to the jury are established, however, a district court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise, which if not done can render expert testimony unreliable” *Id.*

“When faced with a proffer of expert scientific testimony, the trial court must make ‘a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’” *Polski*, 538 F.3d at 838 (*quoting Daubert*, 509 U.S. at 592-93). Thus, under Rule 702, the trial judge also acts as a gatekeeper by screening evidence for relevance and reliability. *Daubert*, 509 U.S. at 589.

The district court applies a three-part test when screening expert testimony under Rule 702:

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Polski, 538 F.3d at 839 (quoting *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001)).

When assessing the reliability of expert testimony, a trial court should consider several factors, including: “(1) whether the concept has been tested, (2) whether the concept has been subject to peer review, (3) what the known rate of error is, and (4) whether the concept is generally accepted by the community.” *Miller v. Baker Implement Co.*, 439 F.3d 407, 412 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 593-95). There is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be “tied to the facts” of the particular case. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (quoting *Daubert*, 509 U.S. at 591).

III. BACKGROUND

In his report and deposition testimony, Dr. Wenzel agreed with Plaintiffs on a number of important points. First, Dr. Wenzel agrees that total hip and total knee replacement surgeries are considered “clean surgeries.” Ex.A, Wenzel Dep. at 234:24-235:1; 311:25. Dr. Wenzel agrees that periprosthetic joint infections are deep (not superficial) infections. *Id.* at 302:6-8. He agrees that bacteria must land on the prosthetic implant during surgery in order for a patient to develop a periprosthetic joint infection. *Id.*

at 216:18-22, 278:1-25. Dr. Wenzel further agrees that regardless of any comorbidity—diabetes, immunosuppressed, obesity—periprosthetic joint infections do not occur without bacteria. *Id.* at 277:15-23.

Dr. Wenzel also agrees that a number of possible causes of infection can be excluded. Dr. Wenzel agrees that bacteria do not come from, and infection is not caused by, the following:

- anesthesia machines;
- surgical lights;
- computer monitors;
- computer consoles;
- electrocautery devices;
- bovie;
- surgical drapes;
- cabinets along the walls;
- the suction drain;
- sterilized surgical equipment;
- drop buckets;
- trash receptacles; or
- surgeons moving their hands.

Id. at 99:4-11; 99:19-24; 99:25-100:4; 100:5-12; 100:13-16; 100:18-23; 100:24-101:5; 101:6-10; 101:11- 18; 102:7-14; 103:3-7; 103:8-11; 103:12-104:2.

While Dr. Wenzel agrees with the above opinions of Plaintiffs' and Plaintiffs' experts, eventually two roads diverge: periprosthetic joint infections are caused by either (1) bacteria on the patient's skin at the surgical site; or (2) airborne bacteria stirred up by the Bair Hugger forced warming device. Dr. Wenzel explores each road, but he ultimately chooses the road never traveled *i.e.*, he favors a tenuous and unsupported conclusion that airborne pathogens are somehow unlikely or unable to reach the patient's joint, leaving only the surface of the patient's own skin—no matter how well prepped and clean—as the default source of microbial contamination as discussed below.

Dr. Wenzel offers the following general causation opinions:

- The most likely cause of surgical site infection¹ is the patient's own skin bacteria. *Id.* at 39:20-23; and
- There is not enough information to conclude to a reasonable degree of medical certainty that the Bair Hugger device is generally capable of causing a periprosthetic joint infection. Ex. B (Wenzel Rpt. at 74.)

These are the only opinions, offered by Dr. Wenzel, that speak directly to the issue of general causation. To generate his opinions, Dr. Wenzel conducted a review of the relevant medical literature. Ex. A (Wenzel Dep. at 19:18-23.) In formulating his opinions, however, Dr. Wenzel failed to evaluate the literature in a consistent, scientifically rigorous manner. Instead, he subjectively lifts information out of context from certain studies to support his conclusions. Courts in the Eighth Circuit have found this type of subjective speculation unreliable, and excluded it pursuant to Evidence Rule 702. *See*

¹ The terms "periprosthetic joint infection" and "surgical site infection" are often used interchangeably throughout the reports, depositions, and litigation papers. There is a distinction however; periprosthetic joint infections, also known as deep joint infections, are a specific subtype of surgical site infection; not all surgical site infections are PJI/DJIs.

e.g., *Weisgram v. Marley Co.*, 169 F.3d 514, 521 (8th Cir. 1999) (reversing district court decision to allow expert witness to testify regarding matters about which he could only speculate).

In addition to the above opinions, Dr. Wenzel offers commentary or opinions that are either (1) irrelevant to the issues in this case, or (2) related to areas of medicine in which he has no expertise. Therefore, the Court should exclude this testimony. For the foregoing reasons, and based on the analysis set forth below, the Court should exclude the opinions and testimony of Dr. Wenzel based on lack of reliability under Rule 702.

IV. THE COURT SHOULD EXCLUDE THE TESTIMONY AND OPINIONS OF DR. WENZEL

A. Dr. Wenzel's Opinion that Skin Bacteria at the Surgical Site Cause Periprosthetic Joint Infections is Unreliable

Dr. Wenzel opines that periprosthetic infections are caused by bacteria on the patient's own skin. Dr. Wenzel asserts "that the integrity of the skin is disturbed by the surgery incision, posing a risk of infection: organisms living in harmony in the nose, throat or skin near the incision can find their way to the incision site and cause a surgical infection." Ex. B (Wenzel Rpt. at 22.) This opinion is unreliable because it is not supported by any scientific evidence.

In his deposition, Dr. Wenzel admits that the skin around the surgical site is prepped with alcohol that kills a "high proportion" of the bacteria. Ex. A (Wenzel Dep. at 204:6.) Regardless of the fact that a patient's skin is prepped before surgery (removing a high proportion of bacteria), Dr. Wenzel persists with his theory that the infection causing bacteria come from a patient's skin at or near the surgery site.

Most importantly, Dr. Wenzel's opinion is incomplete. Dr. Wenzel presents only his preconceived notions of the "source" of the pathogenic organisms, while expressing no opinion about the mode of transmission of those germs to the prosthetic device used in total knee and hip implant surgeries like those at issue in this litigation. In fact, Dr. Wenzel cannot offer a single study to account for how the bacteria get from a patient's skin to the prosthetic implant. Indeed, Dr. Wenzel admits he does not even know how bacteria move from the skin and, under his hypothesis, get onto the prosthetic implant—he just asserts a naked opinion that they do. Dr. Wenzel explains his hypothesis as follows:

Q. How do they [the bacteria] move?

A. I don't know how they move, but, you know, they're -- if there -- if there is an incision made across a group of bacteria, then why would you not think that they're actually going to fall into the wound? That's a hypothesis that I have --

Q. Is there any evidence --

A. -- but nobody -- **nobody knows exactly how they get from the flora to the wound.** And I've said that in my report.

Q. Okay. So you have no opinion of how the bacteria get from the flora, patient's flora into the wound; correct?

A. Not in detail. I just know that they're already present at the time of the incision.

Q. Now do they jump from the patient's skin right into the -- into the joint, or would they go through the fascia and the mu -- and the muscle?

A. I don't know.

Id. at 215:19- 216:11.

The deposition testimony above reveals that Dr. Wenzel’s “hypothesis” that periprosthetic joint infections are caused by bacteria on the patient’s skin, is nothing but pure speculation. Dr. Wenzel posits no evidence to support his hypothesis that bacteria move from the patient’s skin to the implant itself.

The lack of evidence for Dr. Wenzel’s opinion is a fatal flaw. No matter which expert is offering it, an opinion based on unsupported speculation is unreliable. *See Glastetter v. Novartis*, 107 F. Supp. 2d 1015, 1045 (E.D. Mo. 2000). Here, “[t]here is simply too great an analytical gap between the data and the opinion proffered.” *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997). The court should not admit opinion evidence “that is connected to existing data only by the *ipse dixit* of the expert,” *Gen. Elec. Co. v. Joiner*, 522 U.S. at 157. Accordingly, because Dr. Wenzel cites no evidence of any kind to support his bald conjecture that bacteria from the patient’s own skin somehow “fall” into the wound, his opinion amounts to *ipse dixit*, which is not helpful to the jury. Therefore, the Court should exclude this opinion, and preclude Dr. Wenzel from offering any such unreliable testimony that periprosthetic joint infections are caused by bacteria located on the patient’s skin near the surgical site.

B. The Court Should Exclude Dr. Wenzel’s Opinion that the Bair Hugger Does Not Cause Periprosthetic Joint Infections

Dr. Wenzel does not necessarily opine that the Bair Hugger device does not cause periprosthetic joint infections; instead, his opinion is that there is insufficient evidence to conclude that *airborne bacteria* are the cause of periprosthetic joint infections.

As a preliminary matter, it is important to note that Dr. Wenzel agrees with a number of important studies supporting Plaintiffs' case. For instance, Dr. Wenzel does not disagree with findings that the Bair Hugger device increases the particle load above the surgical table. Ex. A (Wenzel Dep. at 299.) Dr. Wenzel also admits that particles can carry bacteria; he testified to reading studies that report forty percent (40%) of particles carry bacteria. *Id.* at 50:2-15. And, Dr. Wenzel does not have any opinion on whether operating room traffic (from the surgical team) can cause surgical site infection. *Id.* at 247:19-24.

Ultimately, Dr. Wenzel's opinion rests on an unreliable hodge-podge of information taken out of context from selected literature. The only methodology that Dr. Wenzel even purports to utilize in reviewing the literature is the "Hierarchy of Ascribing Causal Relationships." Ex. B (Wenzel Rpt. at 17.) In his report, Dr. Wenzel cites to an article by Greenlaugh² for this methodology, but fails to establish or even assert that the method is accepted by the scientific community. By failing to supply any actual scientific methodology to develop his opinion, the Court is unable to assess its reliability, including: "(1) whether the concept has been tested, (2) whether the concept has been subject to peer review, (3) what the known rate of error is, and (4) whether the concept is generally accepted by the community." *Miller v. Baker Implement Co.*, 439 F.3d 407, 412 (8th Cir. 2006) (*citing Daubert*, 509 U.S. at 593-95).

² Greenhalgh T., *How to read a paper Getting your bearings (deciding what the paper is about)*, BMJ 1997, 315: 243-6.

Moreover, Dr. Wenzel's methodology (to the extent he has one) for evaluating the literature is applied inconsistently. In his deposition, for instance, Dr. Wenzel criticized the Darouiche³ study for not doing microbiological testing, and for having an insufficient sample size to determine a causal relationship. Wenzel Dep. at 167; 352:6-7. The Darouiche study shows a correlation between bacterial load in the air and periprosthetic joint infections due to the increased bacterial load over the surgical site. *Id.* The findings in Darouiche contradict Dr. Wenzel's opinion that infection causing bacteria originate from the patient's own skin. *Id.* Interestingly, the criticisms he levied against the Darouiche study were not levied against other studies relied on by Dr. Wenzel himself, even those with the same limitations. (Wenzel Rpt. 6-37.)

Dr. Wenzel admits that he extracts favorable data from reports, cites the favorable data out of context, and uses that non-contextual data to support his preformed opinion, even where that study explicitly contradicts Dr. Wenzel's primary opinion. (Wenzel Dep. at 174-176.) Indeed, a hypothetical from Dr. Wenzel's deposition reveals just how far he is willing to go to avoid concluding that the Bair Hugger Device increases periprosthetic joint infections. Dr. Wenzel testified as follow:

Q. Assuming that with all these studies regarding increased particles, increased bubbles, okay, take into consideration Stocks' particle study and Darouiche's CFU study and periprosthetic joint infections, and assume that periprosthetic joint infections are caused by airborne contamination. Would that affect your opinions in this case of whether or not the Bair Hugger increases periprosthetic joint infections?

³ Darouiche, et al., *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*, INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY (2017).

...

A. It's very hypothetical, and as I've told you, **probably not**.

..

Id. at 350:6-22 (emphasis added).⁴ In other words, nothing—not even evidence of airborne contamination of the wound by particles generated by the Bair Hugger—would alter Dr. Wenzel's preconceived belief that the Bair Hugger device cannot contribute to infection in orthopedic device surgeries.

"A reliable opinion must be based on scientific methodology, not subjective belief or unsupported speculation." *Fitzpatrick v. Louisville Ladder Grp., L.L.C.*, 8:99CV29, 2001 U.S. Dist. LEXIS 3305, at *5-6 (D. Neb. Mar. 19, 2001) (citing *United States v. Rouse*, 100 F.3d 560, 567 (8th Cir. 1996)). Furthermore, the expert's opinion must assist the trier of fact in understanding a fact in issue. *Id.* Dr. Wenzel's opinion here does neither.

Dr. Wenzel's conclusions are similar to the expert's conclusions in *Kinergy Corp. v. Conveyor Dynamics Corp.*, No. 4:01CV00211 ERW, 2003 U.S. Dist. LEXIS 28291, at *72 (E.D. Mo. Oct. 14, 2003). In *Kinergy*, the only process that the expert utilized to come up with his conclusions was to look at certain "machines, go through a thought process in his head, and write his report." *Id.* Similarly, Dr. Wenzel merely looked at literature, "thought about it in his head," and wrote his report. Like in *Kinergy*, the review of Dr. Wenzel's opinions above reveals that "[w]hat is called his methodology is in reality his conception of whatever he wants it to be." *Id.* Accordingly, for the same

⁴ Defendant's counsel raised the following objection to this question: "Object to form of the question, incomplete hypothetical, assumes facts not in evidence."

reasons articulated in *Kinergy*, Dr. Wenzel's conclusory and unsupported opinions are unreliable and should be excluded.

Dr. Wenzel's opinion is further unreliable because the opinions he intends to offer in this matter directly contradicts the conclusions he has reached on these issues outside the courtroom. Dr. Wenzel's textbook states, "*Airborne bacteria* originating from the surgical team suffice to create [surgical site infections] in these types of procedures, particularly when implants are being placed (example, total hip prostheses)." *Id.* at 364:1-6 (emphasis added). Dr. Wenzel's textbook also states that the "main source of *airborne bacteria* in the OR originate primarily from the skin of individuals in the room" *Id.* at 364:15-19 (emphasis added). Dr. Wenzel admitted that his text was authoritative. *Id.* at 362:5-365:15. Yet throughout his written report and deposition, Dr. Wenzel was unwilling under any circumstance to opine that airborne bacteria are causes of periprosthetic joint infections.

In 2013, the International Consensus on Periprosthetic Joint Infection⁵ (of which Defendant 3M was a platinum sponsor and attendee) looked at this issue and 93% agreed that the number of **airborne** bacteria around the wound is correlated with the incidence of PJI. The following was stated:

Question 2: Do numbers of bacteria in the operating room environment correlate directly with the probability of surgical site infection?

⁵ Ex. C., Operative Environment, 2014 Orthopaedic Research Society, J. ORTHOP. RES. 32:S60-S80, S60 (2014).

Consensus: We recognize that airborne particulate bacteria are a major source of contamination in the operating room environment and that bacteria shed by personnel are the predominant source of these particles. The focus of our recommendations is to reduce the volume of bacteria in the operating room (*Emphasis supplied.*)

Delegate Vote: Agree: 93%, Disagree: 5%, Abstain: 2% (Strong Consensus)

Justification: Air is a potential source of contamination in the operating room. Studies have demonstrated that the number of airborne bacteria around the wound is correlated to the incidence of PJI. It has been suggested that if it was possible to measure accurately the number of bacteria present in the wound it should constitute the most precise predictor of subsequent infection. Bacteria can be considered as part of the total mass of particulates in the air. Some studies have suggested that the airborne particulate count should be considered as potential surrogate for airborne microbial density. Others have found correlation between the number of particulates larger than 10 micrometers with the density of viable bacteria at the site of surgery (measured by colony forming units). It has been suggested that monitoring particulate count be used as a real-time proxy for increased risk of wound contamination or infection. Persons in the operating room are major source of bacterial load and shed bacterial particulates. These particulates circulate through the operating room via air currents. Movements of objects (personnel and/or operating room equipment including opening and closing doors) can generate significant marked air currents and increase the probability of bacteria being deposited in the surgical site.

Of course, the motivation behind Dr. Wenzel's opinion may well be explained by the fact that he has billed Defendant 3M over \$300,000.00 to generate these opinions and more than eighty percent (80%) of his income comes from this case. Wenzel Dep. at 135:13-15; 136:17-24. Regardless of his motivation, Dr. Wenzel's clear shift of his opinion for purposes of litigation renders his opinion untrustworthy and not reliable under Rule 702.

For the reasons stated above, the Court should exclude Dr. Wenzel's general causation opinion because it is unreliable.

C. The Court Should Preclude Dr. Wenzel from Offering Opinions or Testifying About Comorbidity and Infection Because It Is Irrelevant

Dr. Wenzel's discussion of patient comorbidity is irrelevant to the issue of general causation in this case. Dr. Wenzel admits that *a patient's comorbidity does not cause infection*—bacteria cause infection. Dr. Wenzel explained that bacteria are necessary for infections as follows:

Q. Okay. You still need the bacteria to land on the -- the diabetic and obese person; correct?

A. Correct.

Q. If no bacteria lands on the joint during the operation of a diabetic obese patient, that patient, more likely than not, is not going to have an infection; correct?

A. Yes.

Id. at 277:15-23.

Accordingly, Dr. Wenzel's discussion of comorbidity speaks only to a patient's vulnerability or susceptibility to infection, not to causation itself.

The court must determine not only if the testimony is reliable, but also whether it has a valid connection to the pertinent inquiry. *Kumho Tire Co.*, 526 U.S. 137 at 149. Expert testimony must therefore “logically advance[] a material aspect of the proposing party's case.” *Daubert*, 509 U.S. at 597. Dr. Wenzel's discussion of comorbidity simply does not logically advance a material aspect of the case (general causation).

Expert testimony also must be “sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.” *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir.) (citing *Daubert's* “fit” requirement), *cert. denied*, 531 U.S. 979 (2000). This case is not about comorbidity or susceptibility to infection. “[A] tortfeasor takes his victim as he finds him.” *Schaub v. VonWald*, 638 F.3d 905, 937 (8th Cir. 2011). Any discussion of any given plaintiff’s comorbidity therefore would not assist the trier of fact in determining the issue of general causation. “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591 (1993). Dr. Wenzel’s opinions regarding comorbidity are irrelevant and will only confuse the trier of fact. *Kinergy*, No. 4:01CV00211 ERW, 2003 U.S. Dist. LEXIS 28291, at *42 (expert witness testimony excluded when opinions “are irrelevant to the action and will only confuse the trier of fact.”)

Accordingly, this Court should exclude any testimony or sections of Dr. Wenzel’s report related to comorbidity or patient susceptibility to infection. Ex. B (Wenzel Rpt. at 10-13, 21-22,72); Ex. A (Wenzel Dep. at 273-76.)

D. Dr. Wenzel is Unqualified to Offer Expert Testimony on Certain Topics Included in his Report

Dr. Wenzel intends to offer testimony regarding certain topics even though he admits he is not an expert in those areas. “If an expert is not qualified to opine in a particular area . . . such testimony is excluded under *Daubert*.” *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1047 (D. Minn. 2007). Accordingly, the Court should preclude Dr. Wenzel from testifying regarding the following areas addressed below:

1. Hypothermia

In his deposition, Dr. Wenzel admits that he is not an expert on “hypothermia”, yet intends to testify that normothermia serves to prevent infection during surgery. Wenzel Dep. at 144; *See generally* Wenzel Rpt. Dr. Wenzel is not qualified to present testimony regarding the benefits or detriments of normothermia or hypothermia as he is not an expert in either area, as required by Rule 702, and *Daubert*. Accordingly, Dr. Wenzel’s testimony regarding those subject areas must be excluded.

2. Laminar Airflow

Dr. Wenzel admits that he is not an expert in laminar air flow, and would “love to know more about laminar flow”, yet intends to testify that laminar air flow provides no significant benefit in terms of prevention of surgical site infections. Wenzel Dep. at 42, 44; *See generally* Wenzel Rpt. Dr. Wenzel confirms he is not an expert in operating room airflow, or particle airflow. Wenzel Dep. at 145. Dr. Wenzel agrees he is not an expert in the field of thermodynamics. *Id.* at 150.

Dr. Wenzel is unqualified to present testimony regarding laminar airflow or thermodynamics, as he concedes he lacks expertise either area. Accordingly, his testimony regarding those subject areas must be excluded pursuant to Rule 702 and *Daubert*.

V. CONCLUSION

Defendant 3M has failed to meet its burden to admit Dr. Wenzel’s opinions. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007) (explaining that the party seeking admission of expert testimony has the burden of demonstrating its

reliability). Dr. Wenzel's general causation opinions are unreliable and irrelevant. Dr. Wenzel's opinion that periprosthetic joint infections are caused by bacteria from the patient's skin near the surgical site fails to account for the most important question in this case—how the bacteria make their way to the deep joint space and the prosthesis, without which no deep joint infection will occur. Without at least some scientific evidence to explain how bacteria “jump” from the patient's skin onto the prosthetic device or are otherwise transported to the deep joint space, “there is simply too great an analytical gap between the data and the opinion proffered.” *Joiner*, 522 U.S. at 145–46.

Furthermore, Dr. Wenzel's opinion that the Bair Hugger medical device is not capable of causing PJIs lacks any recognized or specific scientific methodology. Dr. Wenzel identifies no scientific methodology, and instead merely applies his critiques of the relevant literature, and even then he does so inconsistently. As such, Dr. Wenzel's opinion is merely “subjective speculation that masquerades as scientific knowledge.” *Glastetter v. Novartis Phar. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Last, Dr. Wenzel's discussion of comorbidity does not advance the inquiry in this case one scintilla. His discussion—which even he concedes is a hypothesis—is irrelevant and would only serve to confuse the jury.

Accordingly, the Court should **GRANT** Plaintiffs' motion and exclude Dr. Wenzel's opinion testimony.

Respectfully submitted,

Dated: September 12, 2017

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